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10/679,638	10/06/2003	Henrik Bengtsson	6513.200-US	3945

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EXAMINER	
ALEXANDER, JOHN D	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 01/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/679,638	BENGTSSON, HENRIK	
	Examiner	Art Unit	
	John D. Alexander	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *November 7, 2005, After Non-Final Amend*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *4 and 5* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 6-13* is/are rejected.

7)☐ Claim(s) *4 and 5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *November 7, 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claims 4 and 5 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Here, Claim 4 is a multiple dependent claim that optionally depends from multiple dependent Claim 3. Accordingly, the claims have not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 10/8, 10/9, 12, and 13/12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding Claim 7, the claim recites the limitation "the mounting surface" in lines 4 and 5 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Regarding Claims 10/8, 10/9, 12, and 13/12, the phrase "preferably comprising" makes it unclear whether Applicant has intended to require the pressure-sensitive adhesive element. When examining the claims as to the merits, examiner has assumed that the pressure-sensitive adhesive element is required.

Claim Rejections - 35 USC § 102

Claims 1, 3/1, 6, and 8-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Say et al. (Patent No. 6175752).

- Regarding **Claim 1**, Say et al. disclose a fluid delivery device (Fig. 25, element 250) comprising: a reservoir adapted to contain a fluid and comprising, in a situation of use, associated outlet means, expelling means for expelling a fluid out of the reservoir through the outlet means (Fig. 25, element 260; Col. 54, lines 53-58), a voltage source (Fig. 18B, element 95), a pair of electrodes (Fig. 18B, elements 42 & 42'; Col. 7, lines 14-18 & 23-25; Col. 37, lines 64-67), control means adapted for identifying a predefined condition and applying a voltage between the pair of electrodes resulting in muscle stimulation (Fig. 1, element 44; Fig. 18B, elements 104 & 109; Fig. 25, elements 254, 258, & 262; Col. 7, lines 5-12; Col. 39, lines 61-62; Col. 40, line 13; Col. 45, lines 8-67; Col. 46, lines 12-15). Regarding "expelling means...for..." on line 4 and "control means...for..." on line 9, examiner considers that applicant has invoked 35 U.S.C. 112 6th paragraph and that Say et al. disclose the claimed functions and equivalent means.
- Regarding **Claim 3/1**, Say et al. further disclose the fluid delivery device as defined in Claim 1, wherein the control means is adapted to receive remotely generated commands and to control the fluid delivery device in accordance therewith, the predefined condition belonging to the group of conditions comprising: receiving a command from a predefined groups of commands, receiving a predefined command, and performing a predefined control action in response to a received command (Fig. 18B, element 99; Col. 37, lines 31-32; Col. 43, lines 30-34).

- Regarding **Claim 6**, Say et al. further disclose that the outlet means includes embodiments such as an internal or external infusion pump or syringe injector (Col. 54, lines 55-56), which examiner considers to inherently include a hollow needle in communication with the interior of the reservoir.
- Regarding **Claim 8**, Say et al. disclose a sensor device (Col. 2, lines 13-16) comprising: a sensor means adapted to be inserted transcutaneously through the skin of a subject and capable of being influenced by a body substance and producing a signal corresponding thereto (Fig. 1, element 42; Col. 3, lines 6-16; Col. 5, lines 28-32), control means adapted to receive signals from the sensor means and generate command signals in response thereto (Fig. 1, element 44; Col. 6, lines 55-67; Col. 7, lines 1-12), a voltage source (Fig. 18B, element 95), a pair of electrodes (Fig. 18B, elements 42 & 42'; Col. 7, lines 14-18 & 23-25; Col. 37, lines 64-67), wherein the control means is adapted for identifying a predefined condition on the basis of the command signals and applying a voltage between the pair of electrodes, resulting in muscle stimulation (Fig. 1, element 44; Fig. 18B, elements 104 & 109; Col. 7, lines 5-12; Col. 45, lines 8-67; Col. 46, lines 12-15). Regarding "control means...for..." on line 10 of Claim 8 and "control means for..." on line 7 of Claim 11, examiner considers that applicant has invoked 35 U.S.C. 112 6th paragraph and that Say et al. disclose the claimed functions and equivalent means. However, regarding "sensor means" on line 2 and "control means" on line 5 of Claim 8, examiner considers that applicant has not invoked 35 U.S.C. 112 6th paragraph.
- Regarding **Claim 9**, Say et al. further disclose that the command signals are in the form of a value indicative of a blood glucose level of the subject, and wherein the predefined condition

belongs to the group of conditions comprising: a blood glucose level which is outside a given range, a signal from the sensor means is outside a given range, a low voltage condition for the voltage source, and a preset timer interval (Col. 5, lines 31-32; Col. 7, lines 9-12; Col. 45, lines 8-67).

- Regarding **Claims 10/8, 10/9, and 12**, Say et al. further disclose a mounting surface adapted for application to the skin of a subject, the pair of electrodes being arranged on the mounting surface, the mounting surface comprising a pressure-sensitive adhesive (Fig. 17; Col. 31, lines 63-67; Col. 32, lines 1-16). Examiner considers that, for the embodiment disclosed by Say et al. providing counter and reference electrodes placed on the skin of the subject (Col. 7, lines 23-25), these electrodes are arranged on the mounting surface of the sensor.
- Regarding **Claims 13/11 and 13/12**, Say et al. further disclose that the control means is adapted to receive remotely generated commands and to apply a voltage between the pair of electrodes in response (Fig. 18B, element 99; Col. 37, lines 31-32; Col. 43, lines 30-34).

Claim Rejections - 35 USC § 103

Claims 2 and 3/2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Say et al. in view of Fischell (Patent No. 4619653).

- Regarding **Claim 2**, Say et al. disclose a fluid delivery device as related above in rejection of Claim 1, and further disclose a watchdog circuit that tests operating conditions of the device circuitry and may activate a stimulation warning if an error is detected (Fig. 18B, element 103; Col. 47, lines 33-47). Say et al. do not explicitly disclose that the watchdog circuit tests for a predefined condition belonging to the group of conditions comprising: an actual fluid delivery rate which differs from a preset fluid delivery rate, a pressure in the reservoir,

expelling means or associated outlet means above a preset level, an amount of fluid in the reservoir below a preset level, a flow of current between the pair of electrodes outside a preset range, a low voltage condition for the voltage source, and a preset timer interval. However, Fischell discloses a fluid delivery device that includes generating an electrical stimulation alarm (Col. 8, lines 52-68; Col. 9, lines 1-8) to indicate the occurrence of various system conditions such as a fluid leak, lack of correlation between intended medication pumping and the pumping actually effected, low battery voltage, and low medication reserve (see Abstract, lines 3-10). It would have been obvious to one of ordinary skill in the art at the time of applicant's invention from the teaching of Fischell to modify the fluid delivery device with watchdog circuit of Say et al. to include tests for these conditions. The motivation would have been to enable the device, which operates in a field where safety and reliability are paramount, to inform a patient of less than optimal system performance (Fischell, Col. 3, lines 44-47). Therefore, it would have been obvious to combine Fischell with Say et al. to obtain the invention specified in Claim 2.

- Regarding **Claim 3/2**, as related above, the combination of Fischell ant Say et al. discloses the invention of Claim 2. Furthermore, Say et al. further disclose that the control means is adapted to receive remotely generated commands and to control the fluid delivery device in accordance therewith, the predefined condition belonging to the group of conditions comprising: receiving a command from a predefined groups of commands, receiving a predefined command, and performing a predefined control action in response to a received command (Fig. 18B, element 99; Col. 37, lines 31-32; Col. 43, lines 30-34).

Claims 1, 2, 6, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Joshi et al. (Patent No. 5785688) in view of Van Antwerp et al. (Patent No. 6461329) and Ting-Ching (Patent No. 4432653).

- Regarding **Claim 1**, Joshi et al. disclose a fluid delivery device (Col. 1, lines 5-7) comprising: a reservoir adapted to contain a fluid and comprising, in a situation of use, associated outlet means, expelling means for expelling a fluid out of the reservoir through the outlet means (Fig. 3 & 4, elements 126, 150, 154, & 156; Col. 3, lines 6-11), a voltage source (Fig. 5, element 138; Col. 3, line 16), and control means adapted for identifying a predefined condition and applying an alarm in response thereto (Fig. 5, elements 46 & 52; Col. 3, line 17; Col. 5, lines 32 & 34-36). Regarding "expelling means...for..." on line 4 and "control means...for..." on line 9, examiner considers that applicant has invoked 35 U.S.C. 112 6th paragraph and that Joshi et al. disclose the claimed functions and equivalent means. However, Joshi et al. do not explicitly disclose that the alarm is in the form of a pair of skin-mounted electrodes that provide muscle stimulation. Van Antwerp et al. disclose a fluid delivery device (Fig. 3a & 3b) that provides an alarm to the patient upon detection of particular system conditions, wherein the alarm is in the form of a small electric shock applied between two electrodes placed on the patient's skin (Fig. 10b, elements 56 & 58; Col. 8, lines 39-42 & 46-47; Col. 12, lines 11-15). Ting-Ching discloses a pair of electrodes that are exposed on the backside of a wristwatch to contact the skin of a wearer for providing an alert in the form of electrical stimulation (Figs 5 & 6, elements 103; Col. 1, lines 27-44). Ting-Ching further teaches that such an alert provides advantages over other types, such as sound alarms, because it alerts the wearer without disturbing nearby people (Col. 1, lines 9-

19). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention from the teachings by Van Antwerp et al. and Ting-Ching to modify the fluid delivery device of Joshi et al. to include an alarm in the form of a pair of skin-mounted electrodes that provide muscle stimulation. The motivation would have been to provide an alert to the patient that allows the device to remain inconspicuous (Joshi et al., Col. 3, lines 3-5) and that avoids disturbing nearby people (Ting-Ching, Col. 1, lines 9-19).

- Regarding **Claim 2**, Joshi et al. further disclose predefined conditions that include a pressure above a preset level and the passage of a preset timer interval (Col. 5, lines 32 & 34-36).
- Regarding **Claims 6 and 7**, Joshi et al. further disclose a hollow infusion needle in communication with the reservoir, wherein the needle penetrates the patient's skin and is moveable between a retracted position and a projected one (Fig. 3 & 4, element 150; Col. 6, lines 35-48)

Response to Arguments

Regarding rejection of Claims 1, 8, and 11 under 35 U.S.C. 102(b) as being anticipated by Say et al., Applicant's arguments filed November 7, 2005 have been fully considered but are not persuasive. Examiner respectfully asserts that Say et al. disclose multiple embodiments where at least two electrodes are mounted externally to the body of a subject and in conductive contact with the skin of the subject (Col. 7, lines 23-25; Col. 37, lines 64-67). For example, one possible embodiment is one in which both a counter and reference electrode are used and both are placed on the patient's skin. Another example embodiment is one in which each of the two sensors has it's own counter and/or reference electrodes that are placed on the patient's skin. Regarding the voltage applied between electrodes for stimulation, examiner agrees that Say et al.

are not explicit as to which electrodes are utilized to deliver the disclosed mild electrical shock warning. However, such an explicit disclosure is not required; the applied art must only be inherently capable of the recited functional language. Say et al. disclose that "one of the electrodes... of the sensor" (Col. 7, lines 8-9) is used. Therefore, it seems that any of the Say et al. embodiments that comprise a pair or skin-placed electrodes are inherently capable of applying the voltage for muscle stimulation.

Further regarding Claim 1, Applicant's claim language does not require that the recited components be integrated into a single, unitary device. Even if such a requirement were read into the meaning of "device," this recitation is only provided in Applicant's preamble and, therefore, would not lend patentable weight.

Regarding rejection of Claims 2 and 3/2 under 35 U.S.C. 103(a) as being anticipated by Say et al. in view of Fischell, Applicant's arguments filed November 7, 2005 have been fully considered but are not persuasive. Examiner has not relied upon Fischell for a teaching to provide a pair of external electrodes to provide an alarm. Rather, Fischell provides a teaching to modify the fluid delivery device of Say et al. to include providing the stimulation alarm upon detection of a number of system conditions. Furthermore, the principles taught by Fischell are applicable to both implanted and external infusion systems (Fischell, Col. 1, lines 33-36).

Regarding Applicant's arguments of provided advantages, examiner respectfully asserts that these are general allegations and do not set forth facts that patentably distinguish the language of the claims from the prior art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Alexander whose telephone number is (571) 272-8756. The examiner can normally be reached on Monday-Friday, 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JDA

JEFFREY R. JASTRZAB
PRIMARY EXAMINER
11/20/06